

JAN 02 2008

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 05-042)

In the Application of:)	
)	
Karl, Johann et al.)	
)	
Serial No.: 09/720,006)	Examiner: C. Foster
)	
Filing Date: December 19, 2000)	Group Art Unit: 1641
)	
Title: Improvement of Binding Assays by)	Confirmation No. 5872
Multiepitope Analysis and by Combining)	
Antigen and Antibody Determination)	

FACSIMILE TRANSMITTAL LETTER

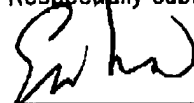
Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Facsimile: 1-571-273-8300
Total Page(s): 9

Dear Sir:

In regard to the above identified application,

1. We are transmitting herewith the attached:
 - a) Response to Office's Requirement for Information of October 1, 2007;
 - b) One Month Petition for Extension of Time; and
 - d) Return Receipt Postcard.
2. With respect to fees:
 - a) Please charge \$120.00 to our Deposit Account No. 13-2490.
 - b) Please charge any underpayment or credit any overpayment our Deposit Account No. 13-2490. A duplicate copy of this Transmittal is enclosed.
3. CERTIFICATE OF FACSIMILE UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1, are being transmitted via facsimile (571-273-8300) to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 2, 2008.

Respectfully submitted,



Emily Miao
Registration No. 35,285

Dated: January 2, 2008

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive, 31st Floor
Chicago, IL 60606
312 913 0001-Telephone
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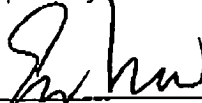
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For: Improvement of Binding Assays by)	
Multiepitope Analysis and by Combining)	
Antigen and Antibody Determination)	

**RESPONSE TO OFFICE'S REQUIREMENT FOR INFORMATION OF
OCTOBER 1, 2007**

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In response to Office's Requirement for Information under 37 CFR §1.105 dated October 1, 2007, Applicants hereby object and respond to the interrogatories as follows.

General Objection

The Office issued a Requirement for Information containing four interrogatories regarding the equation $COI = \text{signal}_{\text{sample}} - \text{background}_{\text{sample}} / n \times \text{background}_{\text{negative control}}$ recited in claim 78. The Office asserts that either the application file or the lack of relevant prior art found in the examiner's search justifies asking the applicant if he or she has information that would be relevant to the patentability determination.

MPEP §704.11 states that "[a] requirement for information under 37 CFR §1.105 places a substantial burden on the applicant that is to be minimized by clearly focusing the reason for the

requirement and the scope of the expected response.” It is clear from the MPEP that such a request for information should only be made when the examiner has a *reasonable basis* for requiring information, and only with *narrowly defined scope*. See MPEP §704.11.

With regard to the content and form of the requirement for information, 37 CFR §1.105 has made it clear that “[i]nterrogatories in the form of specific questions seeking applicant’s factual knowledge” is permitted. MPEP further elaborates on this point by stating that “[t]he terms ‘factual’ and ‘facts’ are included in 37 CFR §1.105 to make it clear that it is facts and factual information, that are known to applicant, or readily obtained after reasonable inquiry by the applicant, that are sought, and that requirements under 37 CFR §1.105 are not requesting opinions that may be held or would be required to be formulated by applicant.” MPEP §704.11.

Further, a reply that the required information is unknown and/or is not readily available to the applicant may be accepted as a complete reply. 37 CFR §1.105(a)(4). Applicants are required by 37 CFR §1.105 to submit information already known, but there is no requirement to search for information that is unknown. MPEP §704.12(a).

Applicants object generally to the interrogatories because the Office does not have a *reasonable basis* for requiring further information. The Office justified its request based on the assertion that Applicants had made admission of prior art by using the phrase “conventional calculation” on page 22 of the specification (See page 3 of the Action). Applicants submit that the phrase as appeared in the English translation of the specification simply means that the concept of calculating a COI is conventional; however, the particular formula shown on page 22 is new. Furthermore, the determination of a test area COI is also new.

Additionally, Applicants respectfully submit that the Office does not have a reasonable basis for requiring further information because the application file already contains reference disclosing other similar equations for calculations of a cut-off index. For example, U.S. Patent No. 6,815,217 (the ‘217 patent), first cited by the Office in the May 30, 2006 Office Action, which undisputedly constitutes part of the application file, discloses a equation for calculation of a cut-off index, though different from the equation recited in claim 78. See Examples of the ‘217 patent. The ‘217 patent has been repeatedly cited by the Office as the basis for the non-statutory double patenting rejection in its May 30, 2006, and February 15, 2007 Office Actions. Thus, the requested information has already been in the application file and known to the Office. Because the requirement for information under 37 CFR §1.105 places a substantial burden on the

applicant and is to be minimized, Applicants respectfully object to the Requirement for Information as redundant and unnecessary.

In addition to the general objection, Applicants hereby specifically object to and respond to each interrogatory as follows.

Interrogatory No.1: What is the source of this equation?

Applicants object to this interrogatory as vague and not narrowly defined. Subject to this objection and the foregoing General Objection incorporated herein, and without waiving these objections, Applicants respond that to the extent of Applicants' knowledge, the equation as appeared in claim 78 was derived from the Applicants.

Interrogatory No. 2: How was this equation derived, and by whom?

Applicants object to the interrogatory because it is not narrowly defined and the Office has not provided any showing as to why the information is reasonably necessary for a determination of patentability. Subject to this objection and the foregoing General Objection incorporated herein, and without waiving these objections, Applicants respond that the equation as appeared in claim 78 was deliberated by the inventors and tested by the inventors to determine the suitability of the equation as a calculation for a cut-off index.

Interrogatory No. 3: Is this equation, or similar calculations of a cut-off index (COD), known in the prior art?

Applicants object to the interrogatory as the interrogatory requests information that goes beyond Applicants' factual knowledge permitted by 37 CFR §1.105. The interrogatory requests, in essence, Applicants' opinion as to the knowledge in prior art and what is and is not prior art. Request for opinion is not explicitly authorized by 37 CFR §1.105 and is disapproved by MPEP §704.11. Applicants further object to the interrogatory because it is vague and not narrowly defined, particularly as to what constitutes "similar calculations" of a cut-off index. Applicants submit that the information is not readily available to the Applicants without further

investigations on whether the equation or similar calculations of a cut-off index are indeed "known in the prior art."

Subject to this objection and the foregoing General Objection, and without waiving these objections, Applicants respond that to the extent of Applicants' knowledge, the equation recited in claim 78 is not known in the art. Additionally, to the extent of Applicants' knowledge, other different calculations such as $COI = (\text{signal}_{\text{test field}} - \text{Signal}_{\text{negative control field}})/3 \times \text{Signal}_{\text{negative control}}$ and $COI = \text{signal}_{\text{sample}} / \text{signal}_{\text{negative sample}}$ have been described in the art.

Interrogatory No.4: Where else is this equation, or similar calculations of a cut-off index (COI), disclosed?

Applicants object to the interrogatory because the Office does not have a reasonable basis for requesting further information when sufficient information is already available to the Office in the application file. Other calculations of a cut-off index are disclosed in, for example, the '217 patent, which was cited repeatedly by the Office, and thus is already in the application file and is known to the Examiner. Because the requirement for information under 37 CFR §1.105 places a substantial burden on the applicant and is to be minimized, the redundant and unnecessary requirement for information is not appropriate.

Subject to the objection and the foregoing General Objection incorporated herein and without waiving these objections, Applicants respond that to the extent of Applicants' knowledge the equation of claim 78 is not disclosed elsewhere, and other similar but different equation for calculating a cut-off index is, for example, disclosed in the '217 patent. *See* Examples of the '217 patent.

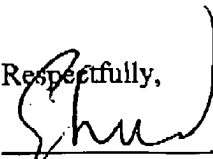
Conclusion

Applicants respectfully submit that the application is in condition for allowance. A favorable decision is earnestly solicited. The petition for one month extension of time and requisite fee is attached hereto. No further fee is believed to be due with this filing. If any further fee is due, however, the Commissioner is authorized to charge the deposit account 13-

2490. If the Examiner deems it helpful, the Examiner is encouraged to call the undersigned attorney at 312-913-2126.

Date: January 2, 2008

Respectfully,


Emily Miao
Registration No. 35,285

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